K 000260

AUG 2 5 2000

North American Medical Corporation
SPINA™ SYSTEM-510 (k) Notification
Revison Date: August 16, 2000- Rev. 3
(This revised page replaces Section VII, 1 thru 4, [pages 16 thru 19 in the original Application]

SECTION VII

SAFETY AND EFFECTIVENESS

[As required by 21 CFR 80.92]

Applicant/ Official contact person: Carlos Becerra, President & CEO
6595 Roswell Rd #811
Atlanta, GA 30328
Tel: (404) 252-4243 or (404) 256-0777
Cell:(678) 429-1768/ Fax (404) 459-6563

Submitter/Manufacturer:	North American Medical Corporation
Date of Summary Preparation:	July 22, 2000
Common Name:	Equipment, traction powered
Classification Panel:	87 OR Orthopedic
Product code:	ITH
Class and Reference Number:	Class II 890.5900

The Device Description

The Spina System™ is designed to apply distraction forces to a patient's lumbar spine. It consists of a tilt bed which is split into two cushions, and a controller unit. The patient is anchored by means of a pelvic harness to the traction connector for a prescribed treatment time.

The Intended Use

The Spina System is intended to provide a program of treatments for relief from pain and disability for those patients suffering with low back pain. A treatment will consist of a physician prescribed treatment period on the Spina System, and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain.

Substantial Equivalence

The Spina System is substantially equivalent to it's predicate devices because of the similarity in materials, design, and intended use.

The Predicate Devices

(1). The Vax- D
(2). The DRS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2000

Mr. Carlos Becerra
President and CEO
North American Medical Corporation
6595 Roswell Road, Suite 811
Atlanta, Georgia 30328

Re: K002260
Trade Name: Spina™ System
Regulatory Class: II
Product Code: ITH
Dated: July 22, 2000
Received: July 25, 2000

Dear Mr. Becerra:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002260

North American Medical Corporation
SPINA™ SYSTEM-510 (k) Notification
July 2000

K002260

Device Name: Spina™ System

INTENDED USE OF THE DEVICE:

The Spina System provides a program of treatments for relief from pain and disability for those patients suffering with low back pain. A treatment will consist of a physician prescribed treatment period on the Spina System, and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves pain associated with herniated discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of inter-vertebral discs, that is, unloading due to distraction and positioning.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002260

Prescription Use X
(Per 21 CFR 801.109)